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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,367	11/25/2003	Samuel M. Shaolian	ENDOLOG.023CPI	4603
20995 7590 05/31/2007 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER SEVERSON, RYAN J	
			ART UNIT 3731	PAPER NUMBER
			NOTIFICATION DATE 05/31/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary

Application No.

10/722,367

Applicant(s)

SHAOLIAN ET AL.

Examiner

Ryan Severson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 24-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 24-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 25 recites the limitation "the first *branch* release element" in lines 1 and 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Trerotola et al. (5,591,226).** Trerotola et al. (hereinafter Trerotola) reference discloses the invention substantially as claimed (see patent).
6. Regarding claims 24 and 26, the elongate catheter body (see figure 2) comprises an outer sheath (26, see figure 4c) and an inner core (the catheter that is inserted into the sheath). The device has a first graft restraint (4a) and a second graft restraint (4b).

7. Regarding claims 25 and 27, each graft restraint is peelable (see figure 4f) by means of a release element (6a and 6a'). The restraint is elongate (the arms 6a and 6a') and flexible and can be moved axially.

Claim Rejections - 35 USC § 103

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. **Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorros (5,720,735) in view of Anderson et al. (5,647,857) and Trerotola et al. (5,591,226).** Dorros reference discloses the invention substantially as claimed, including an inner core (18 and/or 20), a main vessel graft restraint (62), a first branch vessel graft restraint (62), and a second branch vessel graft restraint (60). The main vessel graft restraint is peelable because of the slot (70) that runs down the side of the

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restraint. Restraint (62) in Dorros reference restrains both the main vessel portion (74) and the first branch portion (78) of the implanted device (see Column 7, Lines 11-14).

Restraint (60) restrains the second branch portion (76).

11. However, Dorros reference does not disclose release elements coupled to the first and second peelable covers. Attention is drawn to Anderson et al. (hereinafter Anderson) reference, which teaches a release element (30) may be used with a peelable sheath to allow the sheath to be removed without disturbing the placement of the stent (see Column 5, Lines 53-56). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to couple a release element, as taught by Anderson reference, to the peelable sheaths of Dorros reference to allow the sheaths to be removed without disturbing the placement of the stent.

12. Furthermore, Dorros reference in view of Anderson reference does not disclose an outer sheath that surrounds the graft restraints (60 and 62 of Dorros reference). Attention is drawn to Trerotola reference, which teaches an outer sheath (26a) can surround the graft restraints (4a) to allow the easy insertion of the graft restraints and graft into a vessel. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the outer sheath of Trerotola with the device of Dorros in view of Anderson to allow the easy insertion of the graft restraints and graft into a vessel.

13. Regarding claims 2 and 8, the release element of Anderson is a strand, which is elongate and flexible (see Column 5, Lines 9-10).

14. Regarding claims 3 and 7, both restraints (60 and 62) of Dorros reference are tubular sleeves.

15. Regarding claim 4, the inner core (20) is coaxially disposed within the first tubular sleeve (62) and therefore is interpreted as being coupled to the sleeve. Coupling can be defined as being linked in pairs.

16. Regarding claims 5 and 6, since the same restraint (62) covers both the first branch vessel and main vessel portions of the graft, the "second peelable cover" is interpreted to be the distal portion of restraint (62) which covers the first branch portion of the graft and the first peelable cover, as has been applied to claim 1 above, is the proximal portion of the restraint (62) that covers the main vessel portion of the graft.

17. **Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dorros (5,720,735) in view of Anderson et al. (5,647,857) and Trerotola et al. (5,591,226) as applied to claim 8 above, and further in view of Edoga (5,591,228).**

The combination of Dorros with Anderson and Trerotola references does not disclose the catheter enter through one puncture and the second release element exit through a second puncture. Attention is drawn to Edoga reference, which teaches the body of the cathether may be entered through a first puncture and a portion thereof may exit through a second puncture (see Figure 13) to reduce the possibility of the second release element becoming entangled with the catheter body and the elements that comprise it. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the second release element exit through a different puncture than that which allows the catheter to enter to reduce the possibility of

the second release element becoming entangled with the catheter body and the elements that comprise it.

18. Claims 10 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorros (5,720,735) in view of Burton et al. (5,026,377) and Trerotola et al. (5,591,226). Dorros reference discloses the invention substantially as claimed, including an inner core (18 and/or 20), a bifurcated prosthesis (72) having a main body (74) and first (78) and second (76) branch sections, a first tubular cover (62) compressing the first branch, and a second tubular cover (60) compressing the second branch (see Figures 5-6). Restraint (62) in Dorros reference restrains both the main vessel portion (74) and the first branch portion (78) of the implanted device (see Column 7, Lines 11-14). Restraint (60) restrains the second branch portion (76). The main tubular cover is peelable because of the slot (70) that runs down the side of the cover.

19. However, Dorros reference does not disclose a distal tip coupled to the inner core. Attention is drawn to Burton et al. (hereinafter Burton) reference, which teaches a tip (7) attached to the inner core to provide a smooth transition between the tip and the restraint upon implantation of the device. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a tip, as taught by Burton reference, with the inner member of Dorros reference to provide a smooth transition between the tip and the restraint upon implantation of the device.

20. Further, the device of Dorros in view of Burton does not disclose an outer sheath that surrounds the graft restraints (60 and 62 of Dorros reference). Attention is drawn to Trerotola reference that teaches an outer sheath (26a) can surround the graft restraints

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(4a) to allow the easy insertion of the graft restraints and graft into a vessel. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the outer sheath of Trerotola with the device of Dorros in view of Burton to allow the easy insertion of the graft restraints and graft into a vessel.

21. Regarding claim 12, the first tubular cover (62) is peelable because of the slit (70) that runs down the side of the cover.

22. Regarding claims 13-15, Dorros reference also does not disclose an RO (radiopaque) marker on the outer sheath. Attention is again drawn to Burton reference, which teaches a radiopaque marker (17) may be provided on an outer sleeve (see Column 6, Lines 4-9) to monitor the placement of the instrument in the body using fluoroscopy. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a radiopaque marker, as taught by Burton reference, on the outer sheath of Dorros reference to monitor the placement of the instrument in the body using fluoroscopy.

23. Regarding claim 14, the marker (17) is a band of material as depicted in figure 6 of Burton et al. reference. Figure 6 is a cross-sectional view showing where the band (17) would encircle the outer sheath.

24. Regarding claim 15, the means for marking the sheath with RO material is interpreted to be including a band of RO material on the sheath.

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25. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dorros (5,720,735) in view of Burton et al. (5,026,377) and Trerotola et al. (5,591,226) as applied to claim 10 above, and further in view of Edoga (5,591,228).

The combination of Dorros in view of Burton and Trerotola references does not disclose the prosthesis comprising an expansion spring with an apex and leg portions. Attention is drawn to Edoga reference, which teaches a prosthesis that acts as an expansion spring with an apex (609) and first (601) and second (603) leg portions (see Figure 16) to allow the prosthesis to be self-actuating and to eliminate metal fatigue (see Column 18, Lines 20-31). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the prosthesis of Dorros reference act as an expansion spring with an apex and leg portions, as taught by Edoga reference, to allow the prosthesis to be self-actuating and to eliminate metal fatigue.

Response to Arguments

26. Applicant's arguments, see page 5 of the response, filed 07 March 2007, with respect to the rejection(s) of claim(s) 24 and 25 under 35 U.S.C. 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

However, upon further consideration, a new ground(s) of rejection is made in view of the patent to Trerotola et al. (5,591,226).

27. Applicant's arguments, see pages 6 and 7 of the response, filed 07 March 2007, with respect to the rejection(s) of claim(s) 1 and 10 under 35 U.S.C. 103(a) (particularly with respect to the Del Toro 5,733,267 reference) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further

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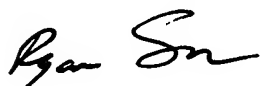
consideration, a new ground(s) of rejection is made in view of the patent to Trerotola et al. (5,591,226).

Conclusion

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Severson whose telephone number is (571) 272-3142. The examiner can normally be reached on Monday - Friday 9:00 - 5:30.

29. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

30. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Ryan Severson
May 23, 2007



ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

5/26/07